(b) the contraceptives which do not have any ill-effect on health and reproduction capability, and

(c) for how long the constant use of such drugs is safe from the health point of view?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ) (a) and (b) There is no scientific evidence that long term use of contraceptive reduces the reproductive capacity The Indian Council of Medical Research has since 1972 evaluated a number of contraceptive preparations for their efficacy, safety and return of fertility, and only those preparations which were found suitable have been recommended for use in the country

(c) All the contraceptives (spacing or terminal) available in the National Family Welfare Programme are safe for long term use These contraceptives are reviewed and approved by the Toxicology Review Panel, Ethical Committee of the Indian Council of Medical Research, and the Drugs Controller General of India prior to carrying out clinical trials for their efficacy, safety and acceptability

Drug permission to DGCI

2053 SHRI KHAN GHUFRAN ZAHIDI Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state

(a) whether it is a fact that the permissions granted by the DGCI for new drugs is much less as compared to the permission granted in 2002,

(b) the names of the drugs and companies approved during the period January, 2002 to November, 2003, and

(c) the new combinations permitted during the same period alongwith the names of the companies?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ) (a) Approval of new drugs is a complex process, and it varies according to the nature of the molecule/drug Therefore, depending upon the nature of the application, time taken for approval varies Approval of new drugs is also subject to the subsmission of all required data as per provisions of the Drugs and Cosmetics Rules

Certain critical drugs *e g* anticancer, anti-HIV etc , which are important from the point of view of public health are however cleared on fast track basis

In the year 2002 (from January to December) 53 New Drugs were approved and from January to November 2003, 35 New Drugs have been approved by the DCG(I)

(b) Names of the approved New Drugs during January 2002 to November 2003, along with names of the companies is enclosed at Statement (*See* below)

(c) Names of the New Combinations permitted during the same period along with names of the companies is enclosed at Statement-II (*See* below)

Statement-I

List of approved new drugs-from January 2002 to November 2003

1	Bimatoprost (Ophthalmic Sol)	Anti-Glaucoma	M/s Allergan India Ltd
2	Meropenem Injection	B-lactum Antibiotic	M/s Astra Zeneca
3	Fosinopril Sodium	Anti-hypertensive	M/s Cadila Pharma
4	Divalproax Sodium	Anti-epileptic	M/s Cadila Health
5	Zaleplon	Sedative-Hypnotic	M/s Torrent Pharma
6	Thymogen Inj	Anticancer	M/s Nicholas
7	Montelukast Sodium	Anti-asthamatic	M/s Ranbaxy Lab
8	Mifepristone	Progesteron antagonist	M/s Cadila Health Care
9	Dexarazoxane inj	Cardio-protective	M/s Ambalal Sarabai
10	Tranexamic acid	Antifibrolytic	M/s Macleod Pharma
11	Bicalutamide	Anticancer	M/s Cipla Ltd
12	Loteprednol etabonate	Ophthalmic	M/s Sun Pharmaceuticals
13	Apraclonodone	Ophthalmic	M/s Cipla Ltd
14	Mizolastine	Antiallergic	Dr Reddy's Lab
15	Ziprasidone	For Schizophrenia	M/s Torrent Pharma
16	Miltefosine	For Kala-Azar	M/s German Remedies
17	Abacavir	Anti HIV	M/s Hetero Drugs

18.	Nadrifloxacin	Antibacterial	M/s Wockhardt Ltd.
19	Tamsulosin	For BPH	M/s. Cipla Ltd.
20	Famciclovir	Anti-viral	M/s Cipla Ltd.
21	Nateglinide	Antidiabetic	M/s. Alembic Lab.
22	Lercanidipine	Antihypertensive	M/s. Sun Pharma-ceuticals
23.	Itopride	Prokinetic agent	M/s. Knoll Pharma
24	Alprostadil inj	For ED in men	M/s. Pharmacia India
25	Vinpocetine	Vasodilator	M/s. Sun Pharma-ceuticals.
26	Quetapine fumarate	Antipsychotic	M/s. Sun Pharma-ceuticals.
27	Isotretinoin	For Acne	M/s Shalaks Pharma
28	Nebivolol	Antihypertensive	M/s Sarvottam Care
29	Sirolimus	Immunosuppressant	M/s. Wyeth Lederle
30	Drotrecogin Alpha	For Severe sepsis	M/s. Eli Lilly
31	Pygenum africum	For BPH	M/s. Banner Pharma
32	Valdecoxib	NSAID	M/s Glenmark Pharma.
33	Thalidomide	For Leprosy	M/s. Dabur India
34	S-Amlodipine	Antihypertensive	M/s Emcure Pharma
35	Cabergoline	For hyperprolactemia	M/s Sun Pharma-ceuticals
36	Butarphenol tarterate	Opoid analgesic	M/s. Aristo Pharma
37	Gemtuzumab	For Myeloid Leukemia	M/s. Wyeth Lederle
38.	Quinapril	Antihypertensive	M/s. Macleod Pharma
39	Valacyclovir	Anti-viral	M/s. Cipla Ltd
40	Fosphenytoin	Anti-epileptic	M/s. Cadila Health Care
41	Ceftiofur sod.	Antibiotic (Vet use)	M/s Aurobindo Pharma
42	Metaxalone	Muscle relaxant	M/s. Sun Pharma-ceuticals
43	Meglumine gadoteric	Contrast Media	M/s. Imaging Products
44	Cefepine hcl	Antibiotic	M/s. Aurobindo Pharma
45	Acamprosate calcium	For alcohol dependency	M/s Sun Pharma-ceuticals
46.	Aztreonam	Antibacterial	M/s. Aurobindo Pharma

47	Tegaserod	For IBS	M/s Torrent Pharma
48	Parecoxib	NSAID	M/s Glenmark Pharma
49	Balsalezide	For ulcerative colitis	M/s Torrent Pharma
50	Cefetemet-pivoxil	Antibacterial	M/s Alembic Ltd
51	Telmisartan	Antihypertensive	M/s Glenmark Pharma
52	Levocetrizine	antihistaminic	M/s Hetero Drugs
53	Poractant alpha	For respiratory distress	M/s Nicholas
54	Cefprozil	Antibiotic	M/s Ranbaxy Ltd
55	Cilostazol	For intermittent claudication	M/s Glenmark Pharmaceuticals
56	EscitalopramOxalate	Anti depressant	M/s Sun Pharma
57	Anastrazole	Anti cancer	M/s Astrazeneca
58.	Rizapriptan	Anti migrain	M/s Cipla Ltd
59	Gadobenate (Dimeglumine IV Injection)	MRI Contrast Medium	
60	Tacrolimus Ointment	Immuno-modulator	M/s Glenmark Pharma
61	Metolazone	Diuretic	M/s Cadila Healthcare
62	Tiotroplum Boromide	Anti asthematic	M/s Cipla Ltd
63	Gadoversetamide Injection	MRI Contrast Medium	M/s Tyco Healthcare
64	Torsamide	Diuretic	M/s Micro Lab
65	Cyproterone Tablet	For Prostatic Cancer	M/s Cipla Ltd
66	Aripiprazole	Anti schizophrenia	M/s Sun Pharma
67	Azelaic Acid	Anti-Acne	M/s. Micro Lab
68	Bendrofluazide	Diuretic	M/s Unichem Ltd
69	Imipenem +Cilastatin	Anti-Bacterial	M/s Ranbaxy Ltd
70	Tirofiban HCl I V	Anti-Platelet	M/s Cadila Healthcare
71	Teriparatide	For Osteoporosis	M/s Eli Lilly & Co
72	Cladribine	Anti-Cancer	M/s Dabur India
73	Tadalafil	For Erectile Dysfunction	M/s Eli Lilly
74	S-Atenolol	Anti-hypertensive	M/s Emcure Pharma
75	Rosuvastatin	Lipid lowering Agent	M/s Astrazeneca
76	Tazarotene	Anti-Acne	M/s Glenmark Pharma
77	Aceclofenac	NSAID	M/s Intas Pharma

78	Ibopamine HCl	Opthalmic	M/s. Cadila Pharma
79.	Trandolapril	Anti-Hypertensive	M/s. Hetero Drugs
80.	Dorzolamide	Opthalmic	M/s. Hetero Drugs
81	Fenoverine	Anti-spasmodic	M/s. Micro Lab
82.	Risedronate Sodium	For Osteoporosis	M/s. Aventis Pharma
83.	Fondaparinux Sodium	LMWH	M/s. Sanofi Synthelabo
84.	Metadoxine	For Hepatic Disorder	M/s. Sun Pharma
85.	Valgancyclovir	For CMV	M/s. Roche
86.	*Isopropyl Unoprostone*	*Ophthalmic*	*M/s. Novartis India*
87.	Amorolfine	Anti-Fungal	M/s. Galderma
88.	Fluvastatin Sodium	Lipid Lowering Agent	M/s. Novartis India

Statement-II

List of combinations permitted during January 2002 to November 2003.

Sr. No.	Fixed Dose Combination	Name of Company(ies)
1	Mometasone furoate + Terbinafin	M/s. Ranbaxy Lab.
2	Rosiglitazone + Metformin	M/s Torrent/Glenmark Pharma
3	Mosapride + MPS	M/s. Intas Pharma/Ontop.
4.	Formeterol+ Budesonide	M/s. Cipla Ltd.
5	Butenafine + Betamethasone	M/s. Glenmark Pharma
6.	Amlodipine + Benazapril	M/s Cipla Ltd.
7.	Sucralfate + Metronidazole	M/s. Starssenburg Pharma
8.	Glycapyrrolate + Neostigmine	M/s. Neon Lab
9.	Betamethasone + Salicylic acid	M/s. Ontop Pharma
10.	Mefenamic acid + Tizanidine	M/s. Blue Cross
11	Latanoprost + Timolol	M/s. Pharmacia India
12	Tobramycin + Fluromethalone	M/s. M.J. Pharma.
13	Betamethasone + Gentamicin	M/s.Ontop Pharma
14.	S- Amlodipine + Losartan	M/s. Encure Pharma

Sr. No.	Fixed Dose Combination	Name of Company(ies)
15	S-Amlodipine + Atenolol	M/s Emcure Pharma
16	Pioglitazone + Glimeperide	M/s Ranbaxy Lab
17	Glimeperide + Metformin	M/s Torrent Pharmaceuticals
18	Rosiglitazone + Glimeperide	M/s Torrent Pharmaceuticals
19	Tramadol + Paracetamol	M/s Cadila Health Care
20	Ramipril + s (-) Amlodipine	M/s Torrent Pharmaceuticals
21	Olanzapine + Fluoxetine	M/s Sun Pharamaceuticals
22	Ciprofloxacin + Ornidzole	M/s Panacea
23	Quinapril + HCTZ	M/s Cipla Ltd
24.	Aspirin + Dipyridamole	M/s Intas Pharma
25.	Cyproterone + Ethinyl Estradiol	M/s Cadila Health Care
26	Pioglitazone + Glimeperide	M/s Glenmark Pharma
27	S- Amlodipine + Lisinopril	M/s Emcure Pharma
28	Valsartan + HCTZ	M/s Novartis India
29	Montelukast + bambuterol	M/s Okasa Pharma
30	Adapeline + Clindamycin	M/s Glenmark Pharma
31	Ramipril + Candisartan	M/s Okasa Pharma
32	Telmisartan + HCTZ	M/s Glenmark Pharma
33	Rofecoxib + Tizanidine	M/s Torrent Pharmaceuticals
34	Losartan + Ramipril	M/s Unichem
35.	Rofecoxib + Paracetamol	M/s Torrent Pharmaceuticals
36	Lamivudine + Zidovudine + Abacavir	M/s Cipla Ltd.,M/s Hetero drugs
37.	Nadifloxacin + Clobetasol	M/s Wockhardt Ltd
38	Lercanidipine + Atenolol	M/s Glenmark Pharma
39	S-Amlodipine + Valsartan	M/s Torrent Pharmaceuticals
40.	S- Atenolol + S- Amlodipine	M/s Emcure Pharma